

K010447

MAR 15 2001

Westaim Biomedical  
Acticoat® Foam Dressing  
Premarket Notification

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**Premarket Notification  
Summary of Safety and Effectiveness**

**1. Trade (Proprietary) Name**

Acticoat® Foam Dressing

**2. Common/Classification Name**

Foam Dressing/Wound or Burn Dressing

**3. Applicant's Name & Address**

Westaim Biomedical, Inc.  
One Hampton Road  
Exeter, NH 03833

**4. Device Classification & Panel**

A final classification for wound/burn dressings has not been implemented; Class II has been proposed by the General & Plastic Surgery Devices Panel.

**5. Predicate Devices**

Acticoat® Antimicrobial Barrier Dressing (K955453)  
Acticoat® Composite Dressing (K983833)  
Rynel® Medical Foam (K951909)  
Epitech® Dressing (K971337)

**6. Performance Standards**

No applicable standards have been established under Sec. 514 of the FD&C Act.

**7. Intended Use and Device Description**

Intended Use:

The Acticoat® Foam Dressing, an addition to the Acticoat® Dressing line of products, is intended as an effective barrier to bacterial penetration. The barrier functions of the dressing may help reduce infection in light to moderately exudative partial and full thickness wounds, including decubitus ulcers, diabetic ulcers, venous ulcers, first and second degree burns, and donor sites.

Device Description:

The Acticoat® Foam Dressing is a highly absorbent hydrophilic polyurethane foam with an Acticoat® coating applied directly to its surface. It has a light gray appearance. The sustained release of broad-spectrum ionic silver may help protect the wound site from bacterial penetration and contamination, while the inner core maintains the moist environment optimal for wound healing.

**8. Biocompatibility**

The biocompatibility of Acticoat® Foam Dressing has been demonstrated through appropriate *in vivo* and *in vitro* tests as well as previous tests on individual components.

**9. Summary of Substantial Equivalence<sup>1</sup>**

The labeled indications and directions for use of the Acticoat® Foam Dressing are equivalent to those of the previously cleared device. The design, materials, and manufacturing methods of the Foam Dressing are similar to those of the predicate previously cleared device and do not raise any new issues of safety and effectiveness.

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<sup>1</sup> Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or classification and is not to be interpreted as an admission or used as evidence in patent infringement litigation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 15 2001

Mr. Steve Chartier  
Manager, Regulatory Affairs  
Westaim Biomedical, Inc.  
One Hampton Road  
Exeter, New Hampshire 03833

Re: K010447  
Trade Name: Acticoat® Foam Dressing  
Regulatory Class: Unclassified  
Product Code: KMF  
Dated: February 13, 2001  
Received: February 13, 2001

Dear Mr. Chartier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

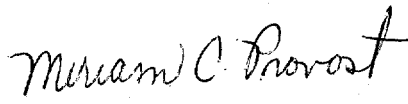
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K010447

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Statement of Intended Use

Acticoat® Foam Dressing

510(k) Number:

Device Name: Acticoat® Foam Dressing

Indications for Use:

The Acticoat® Foam Dressing is an effective barrier to bacterial penetration. The barrier functions of the dressing may help reduce infection in light to moderately exudative partial and full thickness wounds including decubitus ulcers, diabetic ulcers, venous ulcers, first and second degree burns, and donor sites. Acticoat® dressings may be used over debrided and partial thickness wounds.

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K010447

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription  
(Per 21 CFR 801.109)

or

Over the Counter Use  
(Optional Format 1-2-96)